

Notice of Allowability

Application No.

09/996,591

Examiner

Frank W Lu

Applicant(s)

KONDOW ET AL.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 6/24/2003.
2. ☒ The allowed claim(s) is/are 1,3-10,26,28-35,37 and 38.
3. ☒ The drawings filed on 30 November 2001 are accepted by the Examiner.
4. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- * Certified copies not received: _____.
5. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- (a) ☐ The translation of the foreign language provisional application has been received.
6. ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.**

7. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
8. ☐ CORRECTED DRAWINGS must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No. _____.
- (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the Examiner.
- (c) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet.

9. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- 1 ☐ Notice of References Cited (PTO-892)
- 3 ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 5 ☐ Information Disclosure Statements (PTO-1449), Paper No. _____
- 7 ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 2 ☐ Notice of Informal Patent Application (PTO-152)
- 4 ☒ Interview Summary (PTO-413), Paper No. 1/07
- 6 ☒ Examiner's Amendment/Comment
- 8 ☒ Examiner's Statement of Reasons for Allowance
- 9 ☐ Other

DETAILED ACTION

EXAMINER'S AMENDMENTS

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it **MUST** be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Daniel Pereira (Reg. No. 45,518) on January 8, 2007.

2. The application has been amended as follows:

Claim 1 (Currently Amended): A method for determining a nucleotide sequence of a single nucleic acid molecule, which comprises:

(a) immobilizing a nucleic acid molecule onto the surface of a solid, wherein the surface of the solid is an inner wall of a capillary [and a hydrophobic solvent is provided which flows through the capillary];

(b) annealing a primer to said nucleic acid molecule, wherein said primer has a sequence complementary to a part of a sequence of the nucleic acid molecule;

(c) providing a solution which contains a DNA polymerase and only one type of dye-labeled dNTP, where N is A, T or U, G or C, or an RNA polymerase and only one type of dye-labeled NTP, where N is A, U, G or C, to said immobilized nucleic acid molecule, and allowing the dye-labeled dNTP or NTP to react with the 3' end of said primer, whereby the dye-labeled dNTP or NTP, which forms a base-pair with a base in the nucleic acid molecule at a position where the dye-labeled dNTP or NTP reacts with the 3' end of said primer and is bound to the

Art Unit: 1634

primer by action of the polymerase, wherein the dye-labeled dNTP or NTP is labeled with a dye thereby permitting the incorporation of a sequential dNTP or NTP to the 3' end of the dye-labeled dNTP or NTP and wherein said solution consists of a droplet in which an aqueous solution containing said dye-labeled dNTP or NTP, is entrapped within a [the] hydrophobic solvent and the hydrophobic solvent flows through the capillary;

- (d) detecting a bound, dye-labeled dNTP or NTP;
- (e) disrupting the dye molecule of the bound, dye-labeled dNTP or NTP;
- (f) repeating (c) to (e) while changing the type of dye-labeled dNTP or NTP in turn, to sequentially bind dNTPs or NTPs which forms a base-pair with the nucleotides of the nucleic acid molecule; and
- g) determining a nucleotide sequence of the nucleic acid molecule based on the types of the sequentially bound dNTPs or NTPs.

Claim 26 (Currently amended): A method for determining a nucleotide sequence of a single nucleic acid molecule, which comprises:

- (a) immobilizing a primer onto the surface of a solid, wherein the prime comprises a sequence complementary to a part of a sequence in the nucleic acid molecule, wherein the surface of the solid is an inner wall of a capillary [and a hydrophobic solvent is provided which flows through the capillary];
- (b) annealing a nucleic acid molecule to the immobilized primer;
- (c) providing a solution which contains a DNA polymerase and only one type of dye-labeled dNTP, where N is A, T or U, G or C, or an RNA polymerase and only one type of dye-labeled NTP, where N is A, U, G or C, to said immobilized primer, and allowing the dye-labeled

Art Unit: 1634

dNTP or NTP to react with the 3' end of said primer, whereby the dye-labeled dNTP or NTP, which forms a base-pair with a base in the nucleic acid molecule at a position where the dye-labeled dNTP or NTP reacts with the 3' end of said primer and is bound to the primer by action of the polymerase, wherein the dye-labeled dNTP or NTP is labeled with a dye thereby permitting the incorporation of a sequential dNTP or NTP to the 3' end of the dye-labeled dNTP or NTP and wherein said solution consists of a droplet in which an aqueous solution containing said dye-labeled dNTP or NTP, is entrapped within a [the] hydrophobic solvent and the hydrophobic solvent flows through the capillary;

- (d) detecting a bound, dye-labeled dNTP or NTP;
- (e) disrupting the dye molecule of the bound, dye-labeled dNTP or NTP;
- (f) repeating (c) to (e) while changing the type of dye-labeled dNTP or NTP in turn, to sequentially bind dNTPs or NTPs which forms a base-pair with the nucleotides of the nucleic acid molecule; and
- (g) determining a nucleotide sequence of the nucleic acid molecule based on the types of the sequentially bound dNTPs or NTPs.

3. The following is an examiner's statement of reasons for allowance:

Claims 1, 3-10, 26, 28-35, 37, and 38 are allowable in light of the applicant's amendments filed on July 25, 2006 and the examiner's amendments. The closest prior art in the record are Parce *et al.*, (US Patent No. 6,613,513, priority date; February 23, 1999), Dower et al., (US Patent No. 5,547,839, published on August 20, 1996), Cheeseman (US Patent No. 5,302,509, published on April 12, 1994), Anazawa *et al.*, (US Patent No. 6,136,543, 102(e) date: July 30, 1999), Innis et al., (US Patent No. 5,075,216, published on December 24, 1991) and

Art Unit: 1634

Mathies *et al.*, (US Patent No. 5,091,652, published on February 25, 1992). These prior art did not teach that said solution consists of a droplet in which an aqueous solution containing said dye-labeled dNTP or NTP, is entrapped within a hydrophobic solvent and the hydrophobic solvent flows through the capillary in step (c) of claims 1 and 26. These prior art either alone or in combination with the other art in the record does not teach or reasonably suggest a method for determining a nucleotide sequence of a single nucleic acid molecule and a method for determining a nucleotide sequence of a nucleic acid which comprises all of the limitations recited in claims 1 and 26.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

4. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993)(See 37 CAR § 1.6(d)). The CM Fax Center number is (571)273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Lu, Ph.D., whose telephone number is (571)272-0746. The examiner can normally be reached on Monday-Friday from 9 A.M. to 5 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571)272-0735.

Art Unit: 1634

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

January 8, 2007

A handwritten signature in black ink, appearing to read 'Frank Lu', is positioned above the printed name.

FRANK LU
PRIMARY EXAMINER